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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,603	09/01/2000	David Chazan	100/08510	7110

21569 7590 03/31/2003

CALIPER TECHNOLOGIES CORP
605 FAIRCHILD DRIVE
MOUNTAIN VIEW, CA 94043

EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/31/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/654,603

Applicant(s)

Chazan

Examiner

Dwayne K. Handy

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,5 20) ☐ Other:

Art Unit: 1743

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 45-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 45 and 56, applicant recites "the photoimagable polymer layer" and a "second photoimagable polymer layer". There is insufficient antecedent basis for these phrases. For examination purposes, the Examiner assumed applicant was referring to an "ablatable polymer layer".

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1743

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-57 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16, 18, 22-28, 39-58, 61-64, 66-70, 77-79 and 82 of copending Application No. 09/394,012. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 1743

6. Claims 1-8, 10-16, 18, 19, 25-27, 30-43, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Quake et al. (6,221,654 – “Quake”). Quake relates to a microfabricated device and method of using the device for analyzing and sorting of polynucleotides. The embodiment of the device and method most relevant to the instant claims is best shown in Figures 1-5 and columns 7, 15 and 16. In column 7, Quake discloses the basic features of a microfabricated device (20). The device is preferably a silicon microchip (22) containing inlets (24), outlets (26, 28), a plurality of channels (40, 42), and detection and analysis units. Quake recites the method of making (also shown in Figures 5A-5D) in the section title “Microfabrication of Devices” starting in column 15. First, silicon is specified as the preferred substrate at line 50. Then the reference continues in the next column: “...The oxide layer is then coated with a photoresist layer (164), preferably about 1um in thickness. Suitable negative-or-positive-resist materials are well known. Common negative-resist materials include two-component bisarylazide/rubber resists, and positive-resist materials include PMMA and two-component diazoquinone/phenolic resin materials.

“The coated laminate is irradiated through a photomask (166) imprinted with a pattern corresponding in size and layout to the desired pattern of the microchannels. Methods for forming photomasks having desired photomask patterns are well known. For example, the mask can be prepared by printing the desired layout on an overhead transparency using a high resolution printer. Exposure is carried out on standard equipment such as a Karl Suss contact lithography machine.

Art Unit: 1743

In the method illustrated in 5A-5D, the photoresist is a negative resist, meaning that exposure of the resist to a selected wavelength (UV), light produces a chemical change that renders the exposed resist material resistant to the subsequent etching step. Treatment with a suitable etchant removes the unexposed areas of resist, leaving a pattern of bare and resist-coated silicon oxide on the wafer surface, corresponding to the layout and dimensions of the desired microstructures....” As to the other dependent limitations: In column 18, lines 23-32, Quake recites the use of glass as the cover substrate. Spin coating is taught in column 15, line 56. Quake teaches channel in the device to be between about 20 μm and about 500 μm in width and between about 20 μm and about 500 μm in depth. These dimensions would meet the limitations on polymer layer and aspect ratios as claimed by applicant in claims 13, 14, 30 and 36-41.

7. Claims 45-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow (6,167,910). Chow teaches a multilayer microfluidic device system. In general, the system is comprised of multiple stacked layers. Microfabricated elements (grooves, wells, and the like) are manufactured into the surfaces between the various substrate layers. These microfabricated elements define the various microfluidic aspects or structures of the overall device. In preferred aspects, a separate microscale channel network is provided between each of the substrate layers. The device is best shown in Figures 1A-1C and 4, and described in column 6.

From column 6, lines 34-60: An example of a multi-layer microfluidic device according to the present invention is schematically illustrated in FIG. 1. FIG. 1A illustrates the three-layer

Art Unit: 1743

construction of the device from a perspective view. FIG. 1B illustrates a perspective view of an assembled device, e.g., where the layers are mated together. FIG. 1C illustrates a side view of the assembled device. As shown, the device 100 includes multiple substrate layers, such as bottom substrate 102, middle substrate 104 and top substrate 106. Bottom substrate 102 includes a top surface 112, which is mated with the bottom surface 114 of the middle substrate 104. The top surface 115 of the middle substrate 104 is likewise mated with the bottom surface 116 of the top substrate 106. A first channel network 122 is fabricated into the top surface 112 of the bottom substrate 102, as a series of grooves. A similar series of grooves is fabricated into the top surface 115 of the middle substrate 104, to form a second channel network 124. Upon mating the top surface of the bottom substrate with the bottom surface of the middle substrate, these grooves form the channels of the device. Alternatively, the channel network 122 is optionally fabricated onto the bottom surface of middle substrate 104. Upon mating with bottom substrate 102, the channels of the device are formed. This alternate method provides for cost savings where materials for the substrate incorporating the channel networks are substantially more costly than those substrates used as cover layers. Further, alignment of channel networks on different layers of the device is made more simple by their fabrication on a single substrate.” The reference recites the use of laser ablation in fabrication while discussing materials which may be used for the substrate. The materials include: silica based substrates, such as glass, quartz, silicon or polysilicon, as well as other substrate materials, such as gallium arsenide, as well as polymeric materials, such as plastics, such as polymethylmethacrylate (PMMA), polycarbonate,

Art Unit: 1743

polytetrafluoroethylene (TEFLON™), polyvinylchloride (PVC), polydimethylsiloxane (PDMS), polysulfone, and the like. The Examiner believes these cited teachings as anticipating the features of claims 45-56.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1743

10. Claims 20-24 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al. (6,221,654) in view of Chow (6,167,910). Quake, as applied above in paragraph 6 above teaches every element of claims 20-24 except for and polymer layer covered by a third planar substrate and the use of laser ablation to form the channels in the deposited polymer layer. Chow teaches a microfluidic device that includes additional substrate layers above the three layered device shown by Quake that is made from laser ablation of the microstructures. It would have been obvious to one of ordinary skill in the art to combine the laser ablation step from Chow with the method of Quake. One would use laser ablation instead of photoimaging to avoid the extra steps in photoimaging where the substrate is exposed to harsh chemicals. This would save on materials and processing time since the channels would be formed by direct laser exposure. It would have also been obvious to combine the extra substrate/layer teaching from Chow with the method and device of Quake. The addition of an extra level would allow for additional structures such as distribution channels or reservoirs for distributing and/or storing chemicals to be used.

11. Claims 9, 17, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al. (6,221,654) in view of Moles (5,932,799). Quake, as applied above in paragraph 6 above teaches every element of claims 9, 17, 28 and 29 except for the use of photimagable polyimides and adhesive for sealing the polymer layer to the top supporting layer. Moles teaches a microfluidic analyzer module. The module is comprised of multiple polyimide layers (4, 6, 8)

Art Unit: 1743

that are secured to the top support layer (10) through the use of adhesive (col. 9, lines 49-54). It would have been obvious to one of ordinary skill in the art to combine the polyimide polymer layer and the adhesive use from Moles with the method and device of Quake. The addition of the polyimide layer would allow for the use of adhesive on an etched surface to secure the etched polyimide layer to a top layer and form a channel structure.

Conclusion

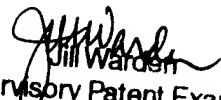
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bentsen et al. (6,375,871), Ryan (6,284,072), Arnold et al. (6,210,986), Soane et al. (6,176,962) and Jons (5,783,452) teach methods of making microfluidic devices. Yang et al. (6,382,254) and van de Goor et al. (6,489,774) recites microfluidic devices which were formed using laser ablation.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

March 24, 2003